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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,756	09/27/2000	Kenneth Rhodes	MNI-070CP4	6507
959	7590	11/17/2003	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

**Application No.**

09/670,756

**Applicant(s)**

RHODES ET AL.

**Examiner**

Joseph F Murphy

**Art Unit**

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 57,58 and 61-64.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 8,10 and 65-67.


Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejections under 35 USC 112 first paragraph of claims 57, 58, 61-62.

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of claims 8, 10, 66-67 under 35 USC 112 first paragraph for lack of enablement has not been overcome by the amendment. The specification does not reasonably provide enablement for an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20 or a polypeptide comprising 15 amino acids of SEQ ID NO: 20, comprising a calcium binding domain, for reasons of record set forth in Paper No. 14, 12/13/2002. Applicant has added the limitation wherein the polypeptides bind and/or modulate a potassium channel activity. However, since detailed information regarding the structural and functional requirements of the peptides are lacking, it is unpredictable as to which encoding variations, if any, meet the limitations of the claims. The specification does not set forth the critical residues for protein function nor does it set forth the amino acid positions at which mutation may be tolerated. Since the claims only set forth that the encompassed polypeptides comprise 15 amino acids of the SEQ ID NO: 20, and given the unpredictability of the protein art, it would require undue experimentation to make an use the claimed polypeptides. The rejection of claims 8, 10, 66-67 under 35 USC 112 first paragraph as lacking written description since the for an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20 or a polypeptide comprising 15 amino acids of SEQ ID NO: 20, comprising a calcium binding domain, for reasons of record set forth in Paper No. 14, 12/13/2002. the specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function.

The rejection of claim 65 is maintained. In the instant case, Applicant has not provided a declaration containing the following: i) a statement all restrictions on the availability to the public of the deposited material so deposited will be irrevocably removed upon the granting of a patent. ii) A statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122. iii) A statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer. iv) A statement by declarant that all statements are true and that all statements made on information and belief are believed to be true; and further that these statements were made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon. .

  
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